B. Braun Medizintechnologie GmbH
Division Medizintechnik
Postfach 11 20
D-34209 Melsungen

K052764
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## 7.0 510(k) Summary

JUN - 9 2006

**APPLICANT:** B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212 Melsungen, Germany

**SUBMITTER:** B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2376

Contact: Scott J. Pease, Mgr., Regulatory Affairs

**DEVICE NAME:** Diacap Ultra Dialysis Fluid Filter

**COMMON OR USUAL NAME:** Dialysis Fluid Filter to Remove Bacteria and Endotoxins

**DEVICE CLASSIFICATION:** Class II, 21 CFR §876.5820, System, Dialysate Delivery, Single Patient, Product Code: FKP

**PREDICATE DEVICE:** K993806 Clarigen, Inc., DialGuard™
K003957 GAMBRO® Renal Products, Dialclear™ Ultrafilter
K983126 Minntech FibreFlo

**DESCRIPTION:** The Diacap Ultra dialysis fluid filter is sterile, non-pyrogenic dialysis fluid filter for use with machines providing hemodialysis treatments. The device is composed of a hollow core polysulfone and polyvinylpyrrolidone membrane, polycarbonate housing and headers (end-caps) with Hansen type connectors, silicone O-rings, and polyethylene port caps.

**INTENDED USE:** The Diacap Ultra dialysis fluid filter is intended to filter bacteria and endotoxins from dialysate used for hemodialysis treatments.

**SUBSTANTIAL EQUIVALENCE:** The Diacap Ultra is similar in indications for use and design to the DialGuard™ Endotoxin Removal Device for treatment of dialysate and dialysis water, previously cleared in Clarigen, Inc. 510(k) K993806, the Dialclear™ Ultrafilter, previously cleared in GAMBRO® Renal Products 510(k) K003957 and the FioberFlo previously cleared in Minntech Corp. 510(k) K983126.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 9 2006

Mr. Scott J. Pease
Manager, Regulatory Affairs
B. Braun Medical, Inc.
901 Marcon Blvd.
ALLENTOWN PA 18109

Re: K052764
Trade/Device Name: DIACAP Ultra Dialysis Fluid Filter
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FKQ
Dated: June 1, 2006
Received: June 2, 2006

Dear Mr. Pease:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## 2.0 Indications for Use Statement



510(k) Number (if known): K052764

Device Name: Diacap Ultra Dialysis Fluid Filter

Indications For Use:

The Diacap Ultra Dialysis Fluid Filter is intended to filter bacteria and endotoxins from dialysate.

Prescription Use ___ X ____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052764